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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation LISA HYDE and MARK HYDE, a married couple, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	No. MD-15-02641-PHX-DGC **PLAINTIFFS' MOTION *IN LIMINE #1* TO EXCLUDE OR LIMIT FDA EVIDENCE THAT IS BEYOND THE SCOPE OF THE COURT'S ORDER** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

MEMORANDUM OF LAW IN SUPPORT

Plaintiffs seek a pretrial ruling limiting FDA evidence that is beyond the scope of the Court's Order.[1] This Court's Order (Doc. 9881) states that although the 510(k) process may not speak to any applicable standard of care, it does have probative value, and that many relevant events would be best understood in the context of the 510(k) process. (Doc. 9881, at 4, 7). The Court held that the parties could "tell the jury about the role of the FDA in its oversight of medical device manufacturers, the regulatory clearance process for devices such as IVC filters, and Bard's participation in the 510(k) process and its

[1] Plaintiffs are neither "re-urging" nor seeking re-consideration of the Court's previous Order (Doc. 9881), but seek to exclude evidence beyond the scope of that Order.

compliance (or lack thereof) with that process" (*id.* at 6), but Bard would be prohibited from presenting evidence that its filters are approved, or that clearance is equal to an FDA finding of safety and efficacy. (*Id.* at 6-7). Yet, much of the FDA evidence admitted during the previous two bellwether trials was unrelated to the 510(k) process and directly or indirectly created an impression that FDA made safety and efficacy determinations by implying and stating "Bard worked hand-in-hand with the FDA", and allowing Bard to present evidence that it conducted a design process with the FDA.[2] Such evidence and argument go beyond the Court's Order allowing evidence "best understood in context" of the 510(k) process and allow Bard to argue that the FDA's actions are dispositive of Plaintiffs' claims.[3] As such, Plaintiffs offer four categories of evidence that should be excluded.

I. <u>Evidence Giving the Impression of FDA's Approval of Bard's Internal Actions</u>

Evidence, such as Trial Exhibits 5879 – 5881[4], that is not related to the 510(k) or post-market surveillance communications with FDA should be excluded[5]. Bard used these exhibits and other FDA evidence related to post-market surveillance beyond the scope of the 510(k) process (i.e., not part of discussions or content of 510(k) application) at trial to imply that FDA approved of Bard's internal actions and policies, e.g., its Design Failure Mode and Effects Analysis ("DFMEA").[6] For example, in the previous trials, Bard used FDA contact reports drafted by Bard employees about conversations with the FDA while no 510(k) applications were pending to report in glowing terms how FDA felt about

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[2] Exhibit A, Booker Slides 6 and 72, and Exhibit B, Trial Tr. *Booker* 03/14/18 at 182:10-11.

[3] Exhibit C, Closing Argument, *Jones v. C.R. Bard, et al*: "Ladies and gentleman, I would submit to you that the most powerful evidence on this issue, whether these designs, or this design, was defective, comes straight from the words of the FDA." Trial Tr. 2476:1-2478:7.

[4] Attached hereto as Exhibits D, E, & F.

[5] FDA evidence related to post-market surveillance is not relevant to the G2x filter design, so it should be excluded for this independent reason where failure-to-warn claims have been dismissed. (Doc. 12007).

[6] Exhibit G, Shari O'Quinn, *Booker v. C.R. Bard, et al.*, Trial Tr. 1549:19-1551:16; 1552:21-1553:18; 1554:18-1558:3.

Bard's activities related to its Dear Doctor letters: "[FDA employee] believes it is very good to send this type of letter and appreciates BPV being so proactive…"[7]. This type of FDA evidence is only relevant to post-market surveillance efforts which are Bard's responsibility as a manufacturer, not relevant to the 510(k) clearance process, and serves as an example of the type of evidence that is beyond the scope of this Court's Order. FDA communications are not required for the jury to understand Bard's internal actions. Bard's own documents and testimony provide context for Bard's actions - the only actions at issue - without reference to the FDA. Moreover, Plaintiffs are precluded from deposing FDA officials; as such, it is prejudicial to allow Bard to use these documents as FDA endorsements. The prejudicial effect of this evidence beyond the 510(k) process gives the impression the FDA was not only approving of Bard's behavior, but Bard also "worked hand-in-hand with the FDA." (*See*, Ex. A). Even with proof that the 510(k) process is a comparative, not a safety process, or that Bard withheld information from the FDA, this evidence is insurmountable and unduly prejudicial.

II. Evidence of Reclassification of IVC Filters Is Not Relevant and Unduly Prejudicial

Plaintiffs request exclusion of evidence related to reclassification – specifically, Trial Exhibit 5877[8], a December 1996 FDA Memorandum - that does not relate to the 510(k) process or to any retrievable filters including Bard's. The "Price Memo", a stale regulatory document to "justify the down classification" of all IVC filters is not cited in Bard's 510(k) applications, and Bard does not use it to explain its filters' 510(k) review. Bard uses it to argue that "known risks associated with this device" were thoroughly investigated by the FDA and to tell the jury "the FDA has a wealth of experience with inferior vena cava filters… ."[9] The evidence is unduly prejudicial as it insinuates (while shielded from cross examination) that down-classification is an adjudication of a

[7] Exhibit. N, Tr. Exhibit 5003, at 5003.0001.
[8] Exhibit H.
[9] Exhibit I, Opening Statement, *Jones v. C.R. Bard, et al*, Tr. Trans. 194:16-21.

particular device's safety, which, even if it were, is still irrelevant since it was not relied upon in the 510(k) clearance process. Bard's use of the document sends the message that FDA deemed Bard's devices safe and effective.[10]

III. Evidence Gratuitously Offered Testimony As to FDA Interactions

Bard's witnesses should be precluded from gratuitously peppering their testimony with commentary about FDA communications unrelated to the 510(k) process. For example, when describing what Bard did to address reports of migration-related adverse events Bard's witness included unsolicited commentary: "We communicated frequently with the FDA to share this information with them as well."[11] Bard's counsel also elicited testimony going beyond Bard's actions by asking if in addition to how Bard acted under certain circumstances if it Bard had also been in communication with FDA, which is not relevant.[12] This is another example of Bard supplementing a description of its conduct with its interactions with the FDA outside the 510(k) process and essentially creating a regulatory-halo effect over Bard's conduct to support the "hand-in-hand" relationship it describes Bard has with the FDA, which Plaintiffs cannot overcome. Bard's witnesses also testified gratuitously and directly that its filters were deemed safe and effective; utterances that make it impossible to un-ring the bell[13].

Conclusion

Accordingly, Plaintiffs respectfully request that this Court limit evidence that is beyond the scope of its Order related to FDA 510(k) evidence as described above

RESPECTFULLY SUBMITTED this 10th day of August 2018.

[10] Exhibit J, Closing Arguments, *Jones v. C.R. Bard et al*, Trial Tr., at 2476:13-2477:18.
[11] Exhibit K, Shari O'Quinn, Trial Tr., at 1503:6-1506:13.
[12] Exhibit L, Shari O'Quinn, Trial Tr. 1507:25-1508:5; 1510:23-1511:17.
[13] Exhibit M, Robert Carr, *Jones v. C.R. Bard, et al.*, Trial Tr.750:2-4 ("They are safe and effective.")

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of August 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine